

## REMARKS

In the final Office Action mailed November 1, 2004, the Examiner rejected claims 1-33. By way of the foregoing amendments, claims 1, 4-6, 9, 10, 12, 14, 22, 29, and 30 have been amended. Claims 3 and 27 has been cancelled. Accordingly, claims 1, 2, 4-26, and 28-33 remain pending in this application. Reconsideration is respectfully requested in light of the foregoing amendments and the following remarks. The foregoing amendments and following remarks are believed to be fully responsive to the final Office Action and render all currently pending claims at issue patentably distinct over the cited references.

### I. Rejections Under 35 USC § 102

Claims 1, 3, 6, 8, 9, 10, 12, 14, and 27 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,066,156 to Yan ("Yan"). The Applicant respectfully traverses the rejection.

Independent claim 1 has been amended and relates to an apparatus for treating a vascular condition that includes, *inter alia*, a balloon having an outer first layer and an inner second layer, wherein the outer first layer flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps.

Independent claim 9 has also been amended and relates to a balloon stent assembly that includes, *inter alia*, a balloon including at least one non-tacky outer layer and at least one inner layer, wherein when the balloon is heated at a predetermined temperature the outer layer flows into gaps formed in the stent while the inner layer does not flow.

Yan discloses a delivery catheter coated with a heat activated adhesive to secure a stent thereon. However, Yan does not disclose ***a balloon having an outer first layer and an inner second layer***, wherein the outer first layer flows into gaps formed in the stent when the balloon stent assembly is heated to a predetermined temperature, and retains the stent on the balloon during intravascular movement and the inner second layer does not flow into the gaps, as recited in claim 1, or ***a balloon having at least one tacky outer layer and an inner layer***, wherein when the balloon is heated at a predetermined temperature the outer layer flows into gaps formed in the stent while the inner layer does not flow, as recited in claim 9. Instead, Yan teaches an adhesive that is brushed, wiped, sprayed, or dipped onto the surface of the catheter.

See col. 6, ll. 24-28. Moreover, there is no mention of an outer layer that flows into gaps formed in the stent when the balloon is heated to a predetermined temperature, as recited in both claims 1 and 9. Thus, claims 1 and 9 and the claims that depend therefrom are not anticipated by Yan. Accordingly, the rejection under § 102 should be withdrawn.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 95/33422 to Stoltze et al. ("Stoltze"). The Applicant traverses these rejections.

Stoltze discloses a catheter system that includes a catheter member having first and second ends, the first end having an inflatable portion, a lumen in fluid communication with the inflatable portion and an expandable stent member attached to the inflatable portion by a bond. The bond may be formed by the same or different material than the balloon surface, such as an adhesive. However, Stoltze does not disclose a balloon having an outer first layer and an inner second layer, as recited in amended claim 1. Thus, claim 1 and dependent claim 2 are not anticipated by Stoltze and, accordingly, the § 102 rejection should be withdrawn.

## **II. Rejections Under 35 USC § 103**

Claims 3-10, 12, 14 and 16-33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stoltze in view of U.S. Patent No. 5,797,877 to Hamilton et al. ("Hamilton").

Claims 3-8 depend from claim 1 and claims 10, 12, 14, and 16-21 depend from claim 9. Therefore, these claims rely on the arguments presented above. Moreover, Hamilton does not make up for the deficiencies of Stoltze. To the contrary, Hamilton teaches against an outer layer that flows into gaps formed in the stent when the balloon is heated to a predetermined temperature, as recited in both claims 1 and 9. Instead, Hamilton discloses using an adhesive between inner and outer layers in order to improve layer bonding. See Figure 2d and col. 6, ll. 20-38.

As for claims 22-33, independent claim 22 relates to a method of retaining a stent on a balloon including the steps of, *inter alia*, mounting the stent onto the balloon and sheathing the mounted stent and balloon with a sheath and independent claim 29 relates to a balloon assembly that includes, *inter alia*, a balloon, a stent disposed on the balloon, and a sheath disposed on the stent and the balloon wherein the sheath is configured to be removed after cooling the heated stent assembly from a predetermined temperature.

The Office Action alleges that Stoltze discloses sheathing the mounted stent and balloon; however, this is inaccurate. Stoltze illustrates a heating device that receives the catheter and stent that is used to cause the catheter surface to soften. See p. 14, ll. 14-23. Nowhere do Stoltze or Hamilton even teach or suggest a sheath. Thus, as neither Stoltze nor Hamilton either alone or in combination disclose at least the elements of independent claims 22 and 29 and the claims that depend therefrom, the Applicant requests withdrawal of these rejections.

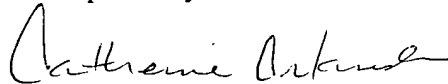
Claims 11, 13, and 15 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Stoltze, in view of Hamilton, and in further view of U.S. Patent No. 5,807,327 to Green et al. ("Green").

Claims 11, 13, and 15 depend from claim 9 and therefore rely on the arguments presented above. Moreover, neither Hamilton nor Green make up for the deficiencies of Stoltze, namely, nowhere do the references teach or suggest an outer layer that flows into gaps formed in the stent when the balloon is heated to a predetermined temperature.

### Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,



---

Catherine C. Maresh  
Registration No. 35,268  
Attorney for Applicant

Medtronic Vascular, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403  
Facsimile No.: (707) 543-5420